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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,414	05/30/2001	Anton-Lewis Usala	35626/234825	7087
826	7590	12/30/2005	EXAMINER	
ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000			GUPTA, ANISH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 09/870,414	<b>Applicant(s)</b> USALA, ANTON-LEWIS	
	<b>Examiner</b> Anish Gupta	<b>Art Unit</b> 1654	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 14 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: \_\_\_\_\_.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
 13. ☐ Other: \_\_\_\_\_.

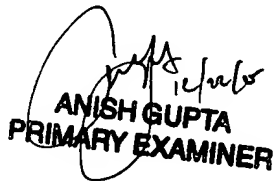
Continuation of 11. does NOT place the application in condition for allowance because: Applicants argue that the rejection does not provide any basis to conclude that vascularizatoin inducing agent will have beneficial effect on ulcer treatment. "The art of record simply does not support the Examiner's statement that inducement of vascularization, by itself, would lead to tissue granulation of would be reasonably expected to be a successful as an ulcer treatment." Applicants further state that at least one known vascularizing agent that has been tried as a diabetic foot ulcer treatment and failed. Applicants recite the David Steed and note that "no clinical trials that have proven FGF to be of benefit in clinical wound healing." Applicants also recite Richard et al. that indicates hat FGF performed no better than a placebo in reducing ulcer perimeter and area. "This clearly establishes that one of ordinary skill in the art, having benefit of the knowledge of the FGF failure, would not expect each and every agent capable of triggering vascularization to automatically find success as an ulcer treatment."

Applicants arguments have been fully amended but have not been found persuasive.

First, Miller et al. teach references implies that that granulation and reepithelialization of the ulcer is desired. The reference states that growth factors "attract fibroblast and other cells involved in early phase of wound healing" can be used. It is known in the art that vascularizatoin is a part of wound healing, see for example the Steed reference cited by Applicants (page 396-397, especially page 397). The reference states that "[e]pithializatoin occurs only after granulation tissue is established." It is well known in the art that granulation of tissue consists of new blood vessel formation, fibroblast activity, and re-epithelialization (see col., lines 29-35 of Davis US 5487899 and Col. 1, lines 28-35 of Pickart et al. US 5059588).

Second, Applicants have relied upon a single reference to establish that one would not expect each and every agent capable of triggering vascularization to automatically find successes as an ulcer treatment. The reference cited by Applicants indicate that PDGF in combination of transforming growth factor and thrombogloublin related peptides accelerated the wound healing rate of chronic diabetic foot ulcers (see page 67). The reference also state that in one study bFGF enhanced slightly healing of venus and diabetic ulcers. The reference goes onto state that bFGF incorporated into a gel or a cream might result in a significant effect since concentration of bFGF decreased by 50% after 4h contact with gauze. Thus, the references do not make the conclusion that agents that have vascularization effects will not work in the treatment of diabetic foot ulcers. Finally it should be noted that Applicants claims are open to the treatment of any ulcer, yet Applicants arguments are concentrated solely on diabetic foot ulcers.

Rejection is maintained.

  
**ANISH GUPTA**  
**PRIMARY EXAMINER**